

Notice of Allowability	Application No.	Applicant(s)	
	10/781,928	SUN ET AL.	
	Examiner	Art Unit	
	Zachary C. Tucker	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12 June 2006.
2. ☒ The allowed claim(s) is/are 1 and 6-8.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____. |
|---|---|

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone between the examiner and applicants' counsel, Vincent P. Liptak, on 19th June 2006.

IN THE CLAIMS –

Claims 3-5 have been **cancelled**.

Claim 8 has been amended as follows:

8. A pharmaceutical composition, comprising a compound or a pharmaceutically acceptable salt ~~of a compound of~~ thereof, according to any one of claims 1, ~~2, 3, 4, 5 or 6~~ and 7, and a pharmaceutically acceptable carrier or excipient.

end of amendments

Response to Amendment

As requested in the correspondence from applicants' counsel, filed 12 June 2006 (hereinafter "present amendment"), which is in reply to the non-final rejection

mailed 10 March 2006 (hereinafter "previous Office action"), claims 1, 6 and 7 have been amended, claims 2 and 9-16 have been cancelled and the specification has been amended at page 23, paragraph [0044].

Election/Restrictions

Pursuant to the present amendment, claims 9-16, which were part of nonelected Group II, have been cancelled.

Claim 8, drawn to a pharmaceutical composition comprising compounds of elected Group I, is hereby therewith, and the Requirement for Restriction between said pharmaceutical composition and chemical compounds is hereby withdrawn.

Claims 3-5, which did not read on the species elected for examination, have been cancelled pursuant to the attached Examiner's Amendment, authorized by applicants' counsel.

Status of Obviousness-Type Double Patenting Rejection

In the previous Office action, claims 1, 2, 6 and 7 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 14 of copending Application No. 10/845,586.

Cancellation of instant claim 2 has rendered moot the rejection of that claim.

In view of applicants' argument in response, which correctly points out that the policy set out in MPEP § 804 I, B directs the examiner to pass to issue an application in which the only outstanding rejection is a *provisional* obviousness type double patenting rejection, the provisional obviousness-type double patenting rejection of the instant claims is dropped.

Status of Claim Rejections - 35 USC § 112

In the previous Office action, claims 6 and 7 were rejected under the first paragraph of this statute, for lack of a disclosure enabling the production of prodrugs of all of the compounds named in said claims.

In view of the present amendment, which deletes "prodrugs" from claims 6 and 7, the rejection is hereby withdrawn.

In the previous Office action, the following points of indefiniteness were identified in the instant claims:

In claims 1 and 2, the term "protected hydroxy" was deemed indefinite. By virtue of the present amendment, the term "protected hydroxy" has been deleted from the claims. Therefore the rejection of claims 1 and 2 on grounds of indefiniteness is hereby withdrawn.

"Aralkyl," recited in claim 1 as an alternative in the definition of variables R₇, R₈ and R₉, was found to be indefinite because the term is defined in the specification as inclusive of the *aryl/alkenyl*_group styrene, calling into question exactly what applicants intended for the term "aralkyl" to actually embrace. In response to the rejection based on the indefiniteness introduced by the unorthodox definition of "aralkyl" presented in the instant specification, applicants have removed styrene as an example of an aralkyl group in paragraph [0044] thereof; the rejection based on the indefiniteness of "aralkyl" in instant claim 1 is hereby withdrawn.

"Wherein n is 0, 1, 2 or 3" in claim 2 was found to lack antecedent basis in claim 1. In response, applicants indicate that variables R₃ and R₄ did include a variable "n" in one of the alternatives, but claim 2 has been cancelled, because R₃ and R₄ have been limited to H only by virtue of the present amendment. Thus, the rejection of claim 2 on ground of indefiniteness is now moot.

The limitation "prodrug," in addition to being non-enabled, under the first paragraph of this statute, was found to be indefinite, as one of ordinary skill in the art could not possibly be apprised of the full scope of what the term embraces, with respect to the compounds named in claims 6 and 7. Applicants' amendment has

deleted "prodrugs" from claims 6 and 7, and therefore the rejection has been withdrawn.

Status of Claim Rejections - 35 USC § 103

In the previous Office action, claims 1 and 2 were rejected under 35 U.S.C. 103(a) as being unpatentable – obvious, that is – over US 6,919,341.

Since claim 2 has been cancelled by the present amendment, the rejection of that claim under this statute is moot.

In view of the present amendment to claim 1, which now limits one of R₁ and R₂ to (optionally substituted) cyclopropyl, R₅ to (optionally substituted) phenyl, and both R₃ and R₄ to H (hydrogen), the rejection is hereby withdrawn.

Declaration

An objection to the declaration was set forth in the previous Office action, because non-initialed, non-dated alterations to co-inventor Ping Huang's entry therein were made.

In view of the replacement for co-inventor Ping Huang's entry in the declaration, the objection to the declaration is hereby withdrawn.

Allowable Subject Matter

Claims 1 and 6-8 are allowed.

The following is an examiner's statement of reasons for allowance:

All of the rejections and objection set forth in the previous Office action have been overcome by applicants' amendment and response. The prior art neither discloses nor suggests any compound according to instant claims 1, 6 and 7, and therefore does not disclose or suggest a pharmaceutical composition according to instant claim 8.

US 5,869,485 (Missbach), US 6,713,474 (Hirst et al) and US 6,919,340 (Currie et al) were cited as examples of the closest prior art in the previous Office action.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Conclusion

All Post-Allowance Correspondence concerning this application must be mailed to:

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Or you can fax them to the Office of Patent Publications at 703-872-9306, in order to expedite the handling of such correspondence as amendments under 37 CFR 1.312; information disclosure statements, and formal drawings. Sending Post-Allowance papers to Technology Center 1600 will only cause delays in matching papers with the case.

For information concerning status of correspondence sent after receipt of the Notice of Allowance, please contact the Correspondence Branch at (703) 305-8027. The Notice of Allowance also has an insert containing contact information on other items, including Issue Fees, receipt of formal drawings and the status of the application.

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A handwritten signature in black ink, appearing to be "Z. H.", with a long horizontal stroke extending to the right.